## Remarks

Further and favorable reconsideration is respectfully requested in view of the foregoing amendments and following remarks.

Thus, claim 1 has been amended to incorporate the subject matter of claim 4, as a result of which claim 4 has been cancelled. In addition, amended claim 1 recites that the amount of water in the adhesive layer is 25 to 60 w/w%, based on the disclosure at page 7, line 28 of the specification.

Claim 6 has been amended to depend from on claim 2, as a result of which claim 14, a duplicate of claim 6, has been cancelled.

Claims 8, 19 and 22 have been amended to be consistent with the water content in amended claim 1.

Claim 9 has been cancelled since it is a duplicate of claim 4, which has now been incorporated into claim 1.

Claims 13, 15 and 21 have been cancelled since they are dependent on cancelled claim 4.

Claim 23 has been amended to recite the preferred water content disclosed at page 8, line 1 of the specification.

The rejection of claims 1-2, 4-6, 8-9, 11, 13-16, 19 and 21-23 under the second paragraph of 35 U.S.C. §112 is respectfully traversed.

Applicant is submitting herewith a copy of "The Japanese Pharmacopoeia (JP XV)", which clearly defines the term "cataplasm" as employed in the present claims. In view of this, Applicant respectfully submits that the rejection of the claims under the second paragraph of 35 U.S.C. §112 should be withdrawn.

The patentability of the presently claimed invention over the disclosures of the references relied upon by the Examiner in rejecting the claims will be apparent upon consideration of the following remarks.

Thus, the rejection of claims 1-2, 4-6, 8-9, 11, 13-16, 19 and 21-23 under 35 U.S.C. §103(a) as being unpatentable over Mooney et al. (US '031) in view of Misumi et al. (US '899) is respectfully traversed.

The present invention relates to a thin aqueous cataplasm prepared by laminating an adhesive layer on a support, the support consisting of a fiber film prepared by heat-fusing a soft plastic resin on a composite fiber prepared by entangling a natural fiber and a soft plastic fiber, or the support consisting of a fiber film prepared by heat-fusing a plastic resin having a soft part and a hard part in common on a fiber consisting of a plastic having a soft part and hard part in common, wherein the adhesive layer consists of 25 to 60w/w% of water, a moisture-retaining agent, polyacrylic acid and/or its salt, a cellulose derivative selected from the group consisting of carboxymethyl cellulose sodium, hydroxypropyl cellulose and hydroxymethyl cellulose, a slightly soluble polyvalent metal salt and a pH controlling agent, and its pH is adjusted to 4 to 6.

Mooney et al. disclose an occlusive wound care dressing comprising a backing material, a support material, an occlusive composition and a porous covering material, as shown in FIG. 7A. The occlusive composition consists of a hydrophobic solvent, a network polymer and a flow control polymer. As the hydrophobic solvent, there are illustrated a hydrocarbon material such as petrolatum, mineral oil, a fatty acid such as castor oil, paraffin wax, microcrystalline wax, beeswax, etc.

Mooney et al describe:

> "A combination of members of two classes of polymers and /or additives should be added to the hydrophobic solvent to make the compositions of this invention. The first class of polymers can be generally termed "network" polymers. . . . . The second class of polymers can be generally "flow control" polymers, which assist in controlling the flow characteristics of the dressings of this invention." (Column 3, lines 36-44)

The network polymers are illustrated in column 3, line 64 to column 4, line 24. The flow control polymers are illustrated in column 4, last line to column 5, line 15.

However, as recognized by the Examiner, Mooney et al. fail to disclose or suggest a composition consisting of **water, a moisture-retaining agent, polyacrylic acid and/or its salt, a cellulose derivative selected from the group consisting of carboxymethyl cellulose sodium, hydroxypropyl cellulose and hydroxymethyl cellulose, a slightly soluble polyvalent metal salt and a pH controlling agent, as required in presently amended claim 1 set forth above.**

In addition, with regard to the fiber film, one prepared by heat-fusing a soft plastic resin selected from polyethylene on a composite fiber prepared by entangling a natural fiber and a soft plastic fiber is not disclosed or suggested by Mooney et al., although a film including polyethylene is disclosed in Mooney et al., as indicated by the Examiner. That is, Mooney et al. mention that the dressings may be coated directly onto a film or fiber, and that such films may be composed of one or more following polymers: polyethylene. . . . . (Column 6, lines 21-29)

The Examiner states that the dressings of Mooney et al. may also be coated onto a fiber substrate which, in turn, is adhesively or otherwise attached to film substrate. However, this film prepared by combining a film and a substrate (adhesively) with pressure sensitive adhesives is different from a fiber film prepared by heat-fusing a film and a substrate.

Whereas Mooney et al. relate to an occlusive wound care dressing which remains in place and does not flow, but has an ointment-like feel (column 1, lines 11-13), on the other hand, Misumi et al. relate to an adhesive **cooling** composition to be directly or indirectly applied to a subject **to cool** the subject by its latent heat in vaporization of water. Therefore, the objects and problems addressed by these references are quite different from each other. The occlusive composition of Mooney et al. cannot be exchanged with the adhesive cooling composition of Misumi et al.

In addition, the adhesive cooling composition of Misumi et al. naturally contains much water, 75 to 95% by weight. [The water contents of Examples 1 to 3 are 92.8, 92.5 and 84.55w/w%, respectively.] On the other hand, the adhesive layer of the present invention contains 25 to 60% (e.g. claim 1), preferably 30 to 50% (claim 23) by weight of water. When the amount of water is beyond 70% by weight, the form-preservation of the base becomes unfavorably weak (page 8, lines 5-6 of the present specification).

Therefore, the present invention is not obvious over Mooney et al. in view of Misumi et al.

Accordingly, in view of the foregoing amendments and remarks, it is submitted that each of the grounds of rejection set forth by the Examiner has been overcome, and that the application is in condition for allowance. Such allowance is solicited.

Respectfully submitted,

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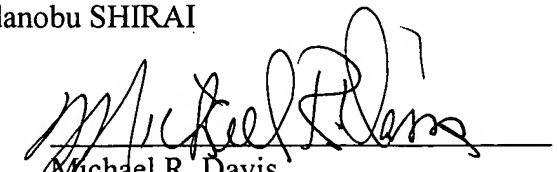
By: 

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January 12, 2009

# *JP XV*

# THE JAPANESE PHARMACOPOEIA

## *FIFTEENTH EDITION*

*Official from March 31, 2006*

English Version

SOCIETY OF JAPANESE PHARMACOPOEIA

## 3. Aromatic Waters

(1) Aromatic Waters are clear saturated solutions of essential oils or other volatile substances in water.

(2) Unless otherwise specified, Aromatic Waters may be usually prepared by the following process. Shake thoroughly 2 mL of an essential oil or 2 g of a volatile substance with 1000 mL of lukewarm purified water for 15 minutes, set the mixture aside for 12 hours or longer, filter through moistened filter paper, and add purified water to make 1000 mL. Alternatively, incorporate thoroughly 2 mL of an essential oil or 2 g of volatile substances with sufficient refined siliceous earth or pulped filter-paper, add 1000 mL of purified water, agitate thoroughly for 10 minutes, and then filter the mixture. To obtain a clear filtrate, repeat the filtration, and add sufficient water through the filter paper to make 1000 mL.

(3) Aromatic Waters have odor and taste derived from the drug substance(s) and excipients used.

(4) Tight containers are used for preservation.

## 4. Capsules

(1) Capsules are preparations in which liquefied, suspended, semi-solid, powdered or granulated drugs or preparations are enclosed in capsules or wrapped with capsule bases. There are two kinds of capsules, which are:

(i) Hard capsules (ii) Soft capsules

(2) Capsules are usually prepared by the following methods.

(i) Hard capsules: Drug substance(s) or uniform mixtures of drug substance(s) with diluents and other suitable excipients, or granules or preparations prepared by a suitable method, are filled as they are or prepared lightly formed and into hard capsules. Extended-release or enteric-coated capsules can be prepared by filling extended-release or enteric-coated preparations into capsules or by changing the components of capsule shells or coating the capsule with suitable coating agents.

(ii) Soft capsules: Drug substance(s) or mixtures of drug substance(s) with suitable diluents, etc. are enclosed by a suitable capsule such as gelatin plasticized by addition of glycerin, sorbitol, etc., and molded in a suitable shape. If necessary, coloring agents, preservatives, etc. may be added to capsule agents. By changing the components of capsule shells or applying suitable coating agents to capsules, extended-release or enteric-coated capsules can be prepared.

(3) Unless otherwise specified, Capsules meet the requirements of the Dissolution Test <*6.10*> or the Disintegration Test <*6.09*>.

(4) Unless otherwise specified, Capsules meet the requirements of the Uniformity of Dosage Units <*6.02*>.

(5) Well-closed or tight containers are used for preservation.

## 5. Cataplasms/Gel Patches

(1) Cataplasms/Gel Patches are generally pasty preparations containing the mixture of drug substance(s) and water or those prepared by spreading the mixture on cloth, which are intended for external use.

(2) Unless otherwise specified, Cataplasms/Gel Patches are usually prepared by mixing drug substance(s) with glycerin, water, or other suitable liquid materials, or with high-molecular-mass materials(s) which are soluble in water or absorbent of water until homogeneity is attained.

(3) Pasty cataplasms which have separated out one or more of their components during storage are rehomogenized before use unless the substances have deteriorated.

(4) Tight containers are used for preservation.

## 6. Elixirs

(1) Elixirs are usually clear, sweetened, and aromatic liquid preparations, containing ethanol, intended for oral use.

(2) Elixirs are usually prepared by dissolving drugs or their extractives in ethanol and purified water, adding aromatic agents and sucrose, other sugars or sweetening agents, and clarifying by filtration or other procedures.

(3) Tight containers are used for preservation.

## 7. Extracts

(1) Extracts are prepared by evaporating the extractives of crude drugs. There are two kinds of Extracts which are:

(i) viscous extracts (ii) dry extracts

(2) Unless other-wise specified, Extracts are prepared as follows.

(i) Crude drugs pulverized in suitable sizes, are usually extracted for a certain period of time with suitable solvents by cold extraction or warm extraction, or by percolation as directed in (2) under Tinctures.

found to contain more than 8 such particles each.

(6) Tight containers are used for preservation.

## 18. Ophthalmic Solutions

(1) Ophthalmic Solutions are aseptic preparations intended for application to the conjunctiva. They are solutions or suspensions of the drug substance(s), or preparations which contain drug substance(s) to be dissolved or suspended before use.

(2) Unless otherwise specified, Ophthalmic Solutions are prepared either by dissolving or suspending drug substance(s) in a prescribed volume of a solvent, or by placing drug substance(s) in tight containers. Every caution is required to avoid contamination in preparing Ophthalmic Solutions. The entire process of preparing Ophthalmic Solutions should be completed as rapidly as possible. The concentration of Ophthalmic Solutions expressed as % of a drug substance indicates w/v%.

Preparations to be dissolved or suspended before use and designated as "for ophthalmic solutions" may be accompanied by a suitable solvent.

(3) Solvents used in the preparation of Ophthalmic Solutions or attached to Ophthalmic Solutions must be harmless in the amounts usually administered and must not interfere with therapeutic efficacy, or with testing.

Solvents for Ophthalmic Solutions are classified into the following two major groups. They should meet the following requirements.

(i) Aqueous vehicles: The usual vehicle for aqueous ophthalmic solutions is purified water or suitable aqueous solutions. Solvents constituted to Ophthalmic Solutions are sterilized, purified water or suitable sterilized aqueous solutions.

(ii) Non-aqueous vehicles: The vehicles for non-aqueous ophthalmic solutions are usually vegetable oils. Also, suitable organic solvents may be used as non-aqueous solvents for some preparations.

(4) The usual particle size observed in suspensions for Ophthalmic Solutions is not larger than 75 $\mu$m.

(5) Unless otherwise specified, no coloring agent may be added solely for the purpose of coloring the preparations.

(6) Unless otherwise specified, sodium chloride or other suitable excipients may be added to aqueous preparations to render them isotonic with lachrymal liquid. Acids or alkalies or other suitable excipients, may be added to aqueous preparations to adjust the pH.

(7) Unless otherwise specified, Ophthalmic Solutions and solvents attached to Ophthalmic Solutions meet the requirements of the Sterility Test <*4.06*>.

(8) Ophthalmic Solutions prepared as aqueous solution and aqueous vehicles attached to Ophthalmic Solutions to be prepared before use should be clear and free from foreign insoluble matter when inspected with the unaided eye at a position of luminous intensity of 3000 to 5000 luxes under an incandescent electric bulb. The containers of Ophthalmic Solutions should have a transparency which does not interfere with the test for foreign matter.

(9) Unless otherwise specified, Ophthalmic Solutions meet the Insoluble Particulate Matter Test for Ophthalmic Solutions <*6.08*>. The limit of the particulates is not more than 1 particle per mL equal to or greater than 300 $\mu$m.

(10) Tight containers are used for preservation.

## 19. Pills

(1) Pills are spherical masses.

(2) Pills are usually prepared by mixing drug substance(s) uniformly with diluents, binders, disintegrators or other suitable excipients, and rolling into spherical form by a suitable method.

(3) Unless otherwise specified, Pills comply with the Dissolution Test <*6.10*> or the Disintegration Test <*6.09*>.

(4) Well-closed or tight containers are used for preservation.

## 20. Plasters and Pressure Sensitive Adhesive Tapes

(1) Plasters and Pressure Sensitive Adhesive Tapes are usually used as topical drugs of external use by spreading or sealing a mixture of drug substance(s), bases and excipients on a cloth or on/in a plastic film, and adhering to the skin in order to deliver the drug substance(s) to the disease sites located to the skin or nearby skin.

(2) Unless otherwise specified, Plasters and Pressure Sensitive Adhesive Tapes are usually prepared by mixing bases such as water soluble or insoluble, natural or artificial high-molecular-mass compound, or their mixture uniformly with drug substance(s) and kneading or sealing on a cloth or film into a suitable shape.

Unless otherwise specified, Plasters and Pressure Sensitive Adhesive Tapes prepared from fats, fatty oils, salts of fatty acids, waxes, resins, plastics, purified lanolin, rubber, or a mixture of the above substances, or prepared by mixing the drug substance(s) with the

above bases uniformly and as a solid at the ordinary temperature, may be described as plasters.

(3) Well-closed containers are used for preservation.

## 21. Powders

(1) Powders are preparations in powdered or finely granulated form.

(2) Powders are usually prepared by uniformly mixing drug substance(s) with or without diluents, binders, disintegrators or other suitable excipients by a suitable method to produce a pulverized or finely granulated form.

(3) When the Particle Size Distribution Test <*6.03*> is performed with Powders, all the powders pass through a No. 18 (850 $\mu$m) sieve and not more than 5% of total powders remain on a No. 30 (500 $\mu$m) sieve. Powders with not more than 10% of total passing through a No. 200 (75 $\mu$m) sieve may be described as Fine Granules.

(4) Unless otherwise specified, Powders for single-dose use meet the requirements of the Uniformity of Dosage Units <*6.02*>.

(5) Well-closed or tight containers are used for preservation.

## 22. Spirits

(1) Spirits are usually alcoholic or hydro-alcoholic solutions of volatile drug substance(s).

(2) Unless otherwise specified, Spirits are usually prepared by dissolving drug substance(s) in ethanol or in a mixture of ethanol and water.

(3) Tight containers are used for preservation, remoting from fire.

## 23. Suppositories

(1) Suppositories are solid preparations intended for insertion into the rectal or vaginal cavity. Suppositories are usually prepared by molding bases into a suitable shape.

Suppositories melt or soften at body temperature or dissolve slowly in the secretions.

(2) Unless otherwise specified, Suppositories are usually prepared by mixing drug substance(s) with fat-type bases, watermiscible bases or other suitable materials, and, if necessary, with emulsifying agents, suspending agents, etc. into a homogeneous mass, and molding it into a suitable shape or coating it with a suitable coating agent, or prepared as a liquid form-fill-seal.

(3) Rectal suppositories are usually conical or spindleshaped, and Vaginal suppositories are globular or oval.

(4) Unless otherwise specified, Suppositories meet the requirements of the Uniformity of Dosage Units <*6.02*>.

(5) Well-closed or tight containers are used for preservation.

## 24. Suspensions and Emulsions

(1) Suspensions and Emulsions are usually liquid preparations of finely divided drug substance(s) suspended or emulsified uniformly in liquid vehicles, respectively.

(2) Suspensions and Emulsions are usually prepared by the following method.

Suspensions: Suspensions are prepared by adding suspending agents or other suitable excipients and purified water or oil to drug substance(s), and suspending to complete uniformity by a suitable method.

Emulsions: Emulsions are prepared by adding emulsifying agents and purified water to drug substance(s), and emulsifying to complete uniformity by a suitable method.

If necessary, preservatives, stabilizers, etc., may be added.

Prepare before use in the case of Suspensions or Emulsions which are apt to deteriorate.

(3) Mix uniformly before use, if necessary.

(4) Tight containers are used for preservation.

## 25. Syrups

(1) Syrups are oral liquid preparations. Syrups are solutions of sucrose, or viscous liquids or suspensions of drug substance(s) containing sucrose, other sugars or sweetening agents.

Syrups include the preparations which are dissolved or suspended before use depending on the properties of the drug substance(s).

(2) Unless otherwise specified, Syrups are usually prepared by dissolving, mixing, suspending or emulsifying drug substance(s) in solutions of sucrose, other sugars or sweetening agents, or in simple syrup. If necessary, the mixtures are boiled and filtered while hot.

(3) Unless otherwise specified, Syrups which are